

CTO Benchmarking Study

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1. Background

At the height of the COVID-19 pandemic, the clinical trials office (CTO) suffered a significant staff shortage (>15 full-time equivalent, or FTE) due to a university-wide hiring freeze preventing replacement of departing CTO staff. After persistent advocacy on behalf of the CTO, a performance review of the CTO was requested.

2. Goals

Key questions were aimed to:

- a) Compare staff number and type, trial mix, and funding sources among CTOs
- b) Understand collaboration and integration of cancer center CTOs within the larger university/hospital system, focus on clinical trial site information (CTSI)
- c) Understand decision making processes and locus of control

Key hypotheses were that large organizations enjoy economies of scale, less siloed organizations are more efficient, and that high performing CTOs are closely integrated with the rest of the cancer research and institutional infrastructure.

3. Methods and Solutions

We partnered with the Indiana University (IU) Kelley School of Business, enlisting five MBA students to conduct the performance review under Kelley faculty supervision. The study was conducted over a three-month period in the spring of 2021. Nine de-identified NCI-Designated Cancer Center CTOs participated. Data was collected for 2018-2020. The main performance metric was total accrual volume per CTO FTE.

4. Outcomes

Total CTO FTEs ranged from less than 80 to over 200, and total yearly accruals ranged from less than 2,000 to over 12,000. Institutions deemed high performing were described as having the following characteristics:

1. Metric-driven management processes
2. High level of financial control over trials with regular review periods
3. Higher number of administrative (versus direct patient/trial management) staff associated with higher performance/accrual efficiency

No correlation was observed between efficiency measures and integration with CTSIs or larger institutional infrastructure. CTO staff composition varied across institutions: 49 to 75 percent trial support staff; 14 to 32 percent regulatory, protocol development, and quality/education staff; and 11 to 19 percent administrative staff. Reliance on dedicated research nurses also varied substantially, ranging from 5 to 40 percent of trial support staff. CTO funding sources varied as well, with industry contracts accounting for <10 to >80 percent and health system support ranging from 0 to >60 percent. All centers

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faced substantial (+/- 15 percent or more) year to year variance in total funding, limiting financial stability.

5. Lessons Learned and Future Directions

Based on this benchmarking study, institutional leaders view of the CTO shifted favorably, and the CTO was allowed to resume hiring and request new positions. The CTO plans to shift our staffing model through attrition, relying less on research nurses and more on non-licensed research professionals to support lower complexity trials. Significant fluctuation in yearly budgets complicates long-term financial planning for CTOs.